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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,767	02/23/1998	WERNER WEITSCHIES	SCH1526	9325

23599 7590 12/03/2002

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/03/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/894,767

Applicant(s)

WEITSCHIES ET AL.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-18, 22-32 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 26-32 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, 8-18, 22-25 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicants continued to traverse the restriction requirement on the ground that the four groups employ the same special technical feature that is the use of ferromagnetic or ferromagnetic substance as labels to detect substances in homogeneous immunoassay, without the need to separate unbound magnetic markers. The special technical feature is taught in the prior art. If the claims are free of prior art, then all the claims should not be restricted. Applicant also argues that restriction requirement is internally inconsistent which clearly shows the artificiality of the groups into which the claims have been divided. Restriction seems to suggest that the difference between groups I and II or between groups III and IV, is the use of magnetic field sensors and external magnetic fields. However, it is submitted that the use of an external magnetic field is needed in order to practice the invention.

Groups (I or II) or groups (III and IV) lack the same special technical feature that is the use of external magnetic field and magnetic field sensors. Group I does not use magnetic field sensors or external magnetic field. If the requirement of using external magnetic field is not required in the claims, then group I does not need an external magnetic field in order to practice the invention. In response to applicant's arguments about the inconsistency of the restriction requirement, the step of using a magnetic field sensor or an external magnetic field is not recited in the claims of group I, that is the how the inventions between the groups are distinguished.

Claim Objection

Claim 22 is objected to because of the following informalities: claim 22 depends on a non-elected claim 3. Claim 22 is required to be dependent upon an elected claim or in an independent form. Appropriate correction is required.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 8-18, 22-25, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all dependent claims, please change "A process" in line 1, to –The process— for proper antecedent basis.

Claims 1 and 2 lack determination step. There is no positive recitation of a contact step between reagents and sample or a correlation step that relates the remanence magnetization to the presence of analyte. The claims are also unclear as to what is being detected to determine the presence of analyte. The claims only recite "determining remanence magnetization" which has no association with the presence of analytes. The claims are also unclear as to how the magnetization determines the presence of analyte, e.g. detecting a rise or drop in this magnetization to detect the analytes.

Claim 8 is unclear of how the sample is moved during measurement, e.g. the means, e.g. detection sensor ?, for moving the sample during measurement.

Newgrounds of Rejection(s)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-42 lack antecedent support for the structure-specific substances" which has not been introduced in claim 1.

Response to Arguments

Applicant's arguments filed February 21, 2001 have been fully considered but they are not all persuasive.

With respect to the objection to claim 22, applicants argue that it is not fully understood why this claim has been singled out for this objection, since various other claims also depend upon non-elected claims.

Claim 22 is the only claim which depends upon a non-elected claim. No other pending claims, among claims 1, 2, 4, 5, 22-25, and 39, depend on a non-elected claim. Claim 22 is required to be in an independent form or dependent upon an elected claim.

Applicant submits that various comments concerning claim 8 are not understood. It is believed that physical movement is intended; for example, at page 8, it is indicated that the signal can be modulated by moving, e.g. by vibration or rotation of the sample.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Although page 8 of the specification

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indicates that the signal is modulated by moving, e.g. by vibration or rotation of the sample, such moving is unclearly recited in the claim.

Remarks

Claims 1, 2, 4, 5, 8-18, 22-25, 39 are free of prior arts.

The prior arts do not teach a method of qualitative and/or quantitative detection of analytes in a liquid and/or solid phase homogeneous assay, comprising determining the remanence magnetization in said homogeneous assay after addition to a sample of a stable or quasi-stable ferromagnetic or ferromagnetic substances.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do
Patent Examiner
December 2, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 1641